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February 26, 2025

Honorable Ann Marie Donio
United States Magistrate Judge
United States Courthouse
4th & Cooper Streets
Camden, New Jersey 08101

Re: ***Salix Pharms., Inc. et al. v. Amneal Pharms. of New York, et al.,***
Civ. No. 24-4607 (ESK/AMD)

Dear Judge Donio:



Plaintiffs respectfully submit this brief reply in response to Defendants Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited's ("Amneal" or "Defendants") February 24, 2025 letter, ECF No. 88, and in further support of Plaintiffs' February 20, 2025 request for leave to amend their First Supplemental Responses to Defendants' First Amended Invalidity Contentions. See ECF No. 87.

Amneal's letter ignores the early stage of proceedings and Plaintiffs' diligence in seeking to amend their responses. The cases cited by Amneal are inapposite. *Blue Gentian v. Tristar Prods., Inc.* involved a request to amend contentions made along with a motion for leave to file a sixth amended complaint made *eleven years* after the case was initially transferred to New Jersey. No. CV 13-1758, 2024 WL 4719560, at *11 (D.N.J. Nov. 8, 2024). *Glob. Sessions LP v. Travelocity.com LP* is similarly inapt to the circumstances here. No. 10-CV-671, 2012 WL 1903903, at *3 (E.D. Tex. May 25, 2012). There the party seeking leave to amend waited nine months to amend its infringement contentions, and the court found that its "original infringement contentions were insufficient." *Id.* The court further found that the defendants had not "fully explain[ed] why amending the contentions . . . [was] important to the case." *Id.* at *6. Amneal has not argued that Plaintiffs' initial responses were deficient, and Plaintiffs here quickly communicated regarding the need to amend their response while discovery is ongoing.

Amneal's characterization of *Auxilium Pharms., Inc. v. Watson Lab'ys, Inc.* is similarly unhelpful here. No. CV 12-3084, 2013 WL 12149760, at *2 (D.N.J. Nov. 11, 2013). The holding cited by Amneal concerned a defendant's request to add contentions for a new theory of invalidity made nearly a year after it could have reviewed the relevant disclosure. *Id.* at *7. Plaintiffs' request here involves adding additional citations, not new contentions. Furthermore, the cases cited by Plaintiffs in their initial letter, see ECF No. 87 at 3, do not support the inflexibility demanded by Amneal. Plaintiffs' request is made early in proceedings, and the substance of the proposed amendment will be included in Plaintiffs' responses(s) to the other defendants' invalidity contentions and thus part of this consolidated litigation irrespective of Amneal's objections.

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Honorable Ann Marie Donio
February 26, 2025
Page 2

What Amneal labels a “serial amendment approach,” see ECF No. 88 at 2, is Plaintiffs’ erring on the side of disclosure by seeking leave to add additional evidence that supports previously-disclosed theories, even if that may not be required by L.Pat. R. 3.4A. See Report and Recommendation at 17-22, *Curia IP Holdings, LLC v. Salix Pharms., Ltd. et al.*, No. 2:21-cv-19293, ECF No. 328 (D.N.J. Feb. 18, 2025) (finding that “[t]he Local Patent Rules do not require a plaintiff to disclose specific evidence to prove its infringement case in its preliminary infringement contentions”) (citing *Fenner Invs., Ltd. v. Hewlett-Packard Co.*, No. 08-cv-273, 2010 WL 786606, at *2 (E.D. Tex. Feb. 26, 2010)).

Finally, Amneal’s only argument regarding prejudice concerns a proposed request for leave to amend infringement contentions that is not yet before the Court, and to which Amneal consented-in-part on February 12. The night before providing its partial consent, Amneal produced FDA submissions and other documents relevant to Plaintiff’s infringement contentions. In order to *avoid* serial amendments, Plaintiffs are reviewing that production and plan to incorporate relevant information into a proposed amendment prior to seeking Amneal’s consent again to our forthcoming request for leave to amend. Amneal’s worries about prejudice are premature and unfounded.

Based on Plaintiffs’ diligence and the current stage of this case, Plaintiffs respectfully request leave to supplement their responses to Amneal’s invalidity contentions as reflected in their initial letter and accompanying exhibit.

Respectfully submitted,

/s Harvey Bartle

Harvey Bartle

cc: Counsel of Record (via e-mail)